C. REMARKS

Pursuant to 37 CFR 1.129, Applicants request that the finality of the rejection mailed on March 18, 2009 be withdrawn.

The claims have been amended in order to place the application in better form.

Claims 74, 84, and 87 have been cancelled without prejudice. Claim 91 has been amended. The fact that Claims 74, 84, and 87 have been cancelled without prejudice is not to be construed as an admission by Applicants or Applicants' attorneys that such claims are not patentable, and Applicants reserve the right to prosecute such claims in a continuing application.

Claims 67-73, 75-86, and 88-91 stand rejected on the grounds of interference estoppel, in that such claims are patentably indistinct from the claims lost in Interference 104,776. This rejection is respectfully traversed.

The present invention, as defined broadly in Claim 67, is directed to an isolated recombinantly produced human papillomavirus (HPV) L1 protein or antigenic fragment thereof, in the absence of human papillomavirus L2 protein. The L1 protein or fragment thereof includes conformational epitopes present on L1 protein on the surface of intact human papillomavirus virions.

Claim 76 is directed to a vaccine for prevention of papillomavirus infection. The vaccine comprises at least one isolated recombinantly produced human papillomavirus L1 protein or antigenic fragment thereof. The vaccine does not include HPV L2 protein. The L1 protein or fragment thereof includes conformational epitopes present on L1 protein on the surface of intact human papillomavirus virions.

Claim 86 defines an isolated recombinantly produced human papillomavirus L1 protein or antigenic fragment thereof, in the absence of HPV L2 protein. The protein or fragment thereof binds to antibodies which recognize conformational epitopes present on an intact human papillomavirus virion. Claim 89 is directed to a vaccine which includes such an isolated

recombinantly produced human papillomavirus L1 protein.

Claim 91 is directed to a method of protecting a human against a papillomavirus infection. The method comprises administering a therapeutically effective amount of a vaccine. The vaccine comprises at least one isolated recombinantly produced human papillomavirus L1 protein or antigenic fragment thereof. The vaccine does not include HPV L2 protein. The L1 protein or fragment thereof includes conformational epitopes present on L1 protein on the surface of intact human papillomavirus virions.

The claims which were lost in the interference were directed to an isolated recombinantly produced human papillomavirus L1 protein, which reproduces the antigenicity and exhibits the same conformation as L1 major capsid protein expressed on the surface of native human papillomavirus virions. The claims which were lost in the interference are directed to a genus. The present claim are directed to a species within such genus, i.e., an isolated recombinantly produced human papillomavirus L1 protein which is made in the absence of human papillomavirus L2 protein.

The prior art had taught, as of the earliest effective filing date of the above-identified application, that in order for recombinantly produced L1 protein to have conformational epitopes present on L1 protein on the surface of intact human papillomavirus virions, such L1 protein needed to be produced in conjunction with L2 protein. Zhou et al., Virology, Vol. 185, pgs. 251-257 (1991), states at Page 253 column 2, lines 5-9 that

> Cells infected with recombinant vaccinia viruses which expressed HPV 16 L1 only, or L2 only, and produced the corresponding protein (L1) or mRNA (L2) did not contain virus-like particles.

Furthermore, Zhou, at Page 255, column 1, lines 16-20 states

> In this study, we have shown that expression of HPV 16 L1 and L2 genes in epithelial cells is both necessary and sufficient to allow assembly of virion-like particles, and the L1 and L2 proteins of HPV 16 are not defective with regard to virion assembly.

Thus, it was understood in the art that, as of the earliest effective filing date of the above-identified application, if one desired to produce HPV L1 protein having conformational epitopes present on L1 protein on the surface of intact human papillomavirus virions, one needed to produce such L1 protein in conjunction with L2 protein. Applicants discovered, contrary to the accepted wisdom of the prior art, that one could produce HPV L1 protein having conformational epitopes in the absence of HPV L2 protein. Therefore, the present claims are patentable over the generic claims which were lost in the interference in that Applicants produced successfully an HPV L1 protein having conformational epitopes in the absence of HPV L2 protein, which the prior art had taught would result in failure.

Therefore, the present claims are patentably distinct from those that were lost in the interference, and it is therefore respectfully requested that the rejection on the grounds of interference estoppel be reconsidered and withdrawn.

Claims 67, 69-77 and 79-91 stand rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for the fragments of L1 including conformational epitopes. This rejection is respectfully traversed.

The present claims are directed to HPV L1 protein or antigenic fragments thereof. The specification, at Pages 11 through 16, clearly shows how one can determine, through means known to those skilled in the art, whether an HPV L1 protein or fragment is antigenic and has conformational epitopes present on intact HPV virions. Therefore, one skilled in the art would be able to determine, by methods known to those skilled in the art, whether a fragment of an HPV L1 protein were antigenic, and had conformational epitopes present on intact HPV virions. Thus, one skilled in the art would be able to determine readily whether a fragment of an HPV L1 protein were within the scope of the claims. Therefore, for the above reasons and others, the specification provides an enabling disclosure with respect to the claimed antigenic fragments of HPV L1 protein, and it is therefore respectfully requested that the rejection under 35 U.S.C. 112,

first paragraph, be reconsidered and withdrawn.

With respect to the rejections under 35 U.S.C. 102(a) and 102(e), Claims 74, 84, and 87 have been cancelled without prejudice. As noted hereinabove, such cancellation is not to be construed as an admission by Applicants or Applicants' attorneys that such claims are not patentable. It is respectfully requested that the rejection under 35 U.S.C. 102(a) and 102(e) be reconsidered and withdrawn.

For the above reasons and others, this application is in condition for allowance, and it is therefore respectfully requested that the rejections be reconsidered and withdrawn and a favorable action is hereby solicited.

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